REMARKS

INTERVIEW WITH THE EXAMINER

Applicant thanks the Examiner for holding a telephonic interview with Applicant and his Counsel on October 10, 2005 regarding the Office Action and proposed amendments and arguments. The present Amendments and Remarks are submitted in view of the interview in order to place the claims in allowance.

THE AMENDMENTS AND REASONS FOR AMENDMENTS

Applicant amends claims 1, 14, 23, 36, and 38. Claims 44 and 45 have been withdrawn from consideration because of a Restriction Requirement. The amended claims add no new subject matter and are fully supported by the application, including the specification, examples, figures, and claims as originally filed.

The amendments are made to clarify the claimed invention in order to expedite the allowance of the present application. Applicant reserves the right to file applications claiming the benefit of priority to the present application claiming the subject matter of the present and other applications.

APPLICANT'S CLAIMED INVENTION IS NOT OBVIOUS UNDER 35 U.S.C. § 103(A) IN VIEW OF THE REFERENCES CITED BY THE EXAMINER

The Examiner rejected claims 1-44 under 35 U.S.C. § 103(a) as allegedly being un-patentable over Baez et al. (US Pat. No. 6,511,809) in view of Reddy et al. (US Pat. No. 5,648,213). The Examiner alleges that Baez et al. teach a method for detecting a compound of interest in a sample similar to the element of the claimed invention, except for addition of surfaces bearing non-nucleic acid binding targets for binding unbound binding constructs. The Examiner further alleges that the Reddy et al.'s teachings makes up for the shortcomings of Baez et al. The Examiner, therefore, alleges that the claimed invention would have been obvious to one of ordinary skill in view of the cited references.

Applicant respectfully disagrees with the Examiner's characterization of the teachings of Baez et al. and Reddy et al. as alleged in the Office Action at issue. Neither Baez et al. or Reddy et al., separately or together, teach or make obvious each and every elements of the claimed invention.

Baez et al. describe in Column 3, lines 33-45, binding of an analyte and at least two reporter conjugates ("nucleic-acid labeled binding constructs") whereby this binding brings the "...nucleic acid labels in close proximity to each other where they may be amplified.... In Column 12, lines 24-32, 33-58 and 55-65, the analyte is first bound on a solid support then the reporter conjugates are bound (lines19-21) and unbound reporter conjugates ("binding constructs") are then washed away (lines 27-28). This protocol is the standard ImmunoPCR format whereby analyte is captured whether already bound to or subsequently bound with reporter conjugate ("binding construct"). Multiple washing steps are then required to remove the bound analyte-reporter complex from the solution of unbound reporter compound. The claimed invention does not wash away unbound reporter conjugate ("binding construct") but **specifically** removes them from the solution containing the reporter conjugate-analyte complex still in the solution. Several important distinctions and advantages of the claimed invention over the teachings of Baez et al. include: a) solution binding of analyte without simultaneous or subsequent solid phase capture of reporter-analyte complex; b) no wash step; c) removal of unbound binding construct by mimetic bearing surfaces in solution phase for the recognition portion of the binding construct; and d) detection by amplification of reporter from solution phase alone.

The steps of the claimed invention are simple compared to the disclosure of Baez et al. involving multiple binding moieties for a captured analyte, a complex hybridization requirement formed by two reporter complexes with an obligatory distance from each other (Column13, 59-67 and Column 14, 1-3) and at least one or more wash steps to remove unbound reporter. The claimed invention uses solution phase capture, wherein nucleic acid conjugated structures bind the analyte of interest in solution, in which the nucleic acid-conjugated binding constructs are the first molecule to bind the analyte of interest, unlike the teaching of Baez et al. where the DNA conjugated structures are the second molecule to bind the analyte of interest. Thus, Baez et al.

does not disclose a method similar to the steps of the claimed invention.

Furthermore, Reddy et al. describe a sandwich assay system that requires an analyte and two immunoreagents, one with an oligonucleotide, one without and both containing an immunoreactivity that is specific for an independent region on the analyte of interest. These analyte-bound immunoreactants are then specifically removed from the solution by a hybridization reaction with an oligonucleotide on a solid support (Column 3 lines 12-19) whereby (Column 3, lines 21-22) the conjugate comprising one of the oligonucleotides is effectively harvested onto the support. The unbound material is effectively washed away (Column 3, lines 23-28). The teaching of Reddy et al. requires two immunoreagents, solid phase capture of immunoreactant-bound analyte, and a wash step or steps to remove unbound immunoreagents. In addition, and importantly, the binding and removal step is specific to the oligonucleotide not the immunoreagent and is not, therefore, a mimetic, analogue, or replica of the immunoreactant, for example, an antibody binding domain, as is the case in the claimed invention where the specific removal is for unbound, **not bound** immunoreagent (" binding construct"). Finally, the captured complex of immunoreactant and analyte must be removed from the solid support to be amplified by PCR.

Moreover, Column 3 lines, 40-49 discusses a competitive assay. In this format only one immunorectant is employed (Column 3 lines 48-49). Here again, however, use is made of complimentary first and second oligonucleotides with one bound to a suitable support (Column 3 lines 49-52). In one competitive assay oligonucleotide-bound analyte or analogue of analyte competes with sample analyte of interest for a labeled immunoreactant and subsequently the target oligonucleotide (Column 3 lines 53-58). Here again, bound and captured analyte of interest is necessary to determine the presence of the analyte of interest which, in this case, involves "... the reduction in binding of label to the support relative to a baseline value in the absence of analyte. Alternatively, the amount of label remaining in solution may of course be determined." (Column 4, lines 27-30).

The Examiner's allegation, therefore, that Reddy et al. involves adding a second non-nucleic acid binding target (competitor) for binding the unbound antibodies, immobilizing to a surface the competitor and unbound antibodies prior to the determination of the compound of interest (Column 3, line 40;Column 4, line 30) is incorrect. Capture of unbound antibodies in the Reddy et al. example is the **means** of detection whereby a reduction in binding is the indicator of the presence of analyte of interest. In the claimed invention, capture of essentially **all,** not a specifically detectable amount (baseline binding), of unbound binding construct is required to allow for analyte detection to occur. The detection of the analyte of interest then occurs via amplification of the reporter DNA template still in the solution phase not from a reduced, detectable signal, the result of competition by the analyte for the reporter molecule binding to a solid support.

The claimed invention is not a competitive assay. The Reddy et al. examples of competitive assay detection of small molecules, therefore, do not make up for the shortcomings of the teachings of Baez et al. In so following, modifying the assay of Baez by the addition of competitor is also not prior art for the SAM Technology.

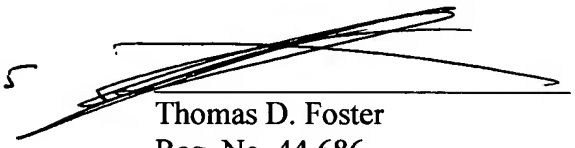
The important distinction for the claimed invention is not the fact that the binding construct and analyte bind in the solution phase but that detection occurs in the solution phase. In this sense, solution phase binding is not a design preference or option but is essential for the claimed invention. The claimed invention also avoids the non-specific binding of binding construct and oligonucleitides to a solid support, an event that requires multiple wash steps and is fraught with assay background issues. Neither Baez et al. nor Reddy et al. offer the advantage of removing unbound, binding construct specifically without altering, binding or otherwise contacting the analyte of interest outside of contact with the immunoreactive binding construct under the favorable conditions of solution phase binding.

Based on the foregoing, Baez et al. and Reddy et al., either separately or together, do not teach, suggest, or provide motivation to make the claimed invention obvious. Thus, the claimed invention is not obvious under 35 U.S.C. § 103(a). Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Applicant respectfully submits that the claims are ready for examination and in condition for allowance.

Respectfully submitted,

Date: 15 November 2005



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